



CENTRALIZED ECG

STUDY AC-060A202: CONTROL

Marco Nief





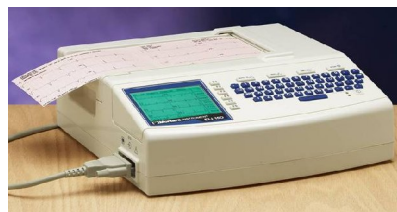
➤ **Actelion Pharmaceuticals Ltd.**

AC-060A202

eResearchTechnology, Inc. (ERT)

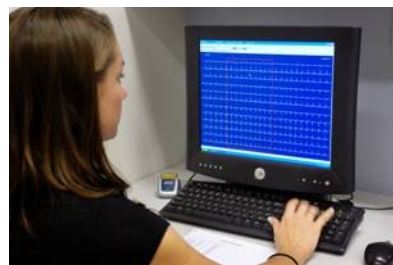
Centralized Digital 12-Lead ECG Services

The ECG Collection Process

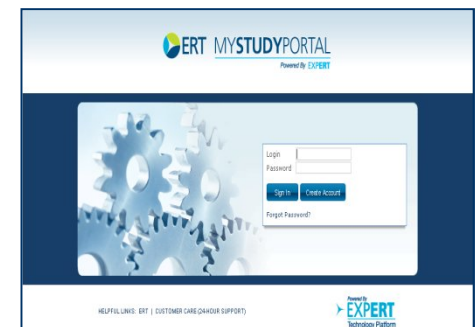
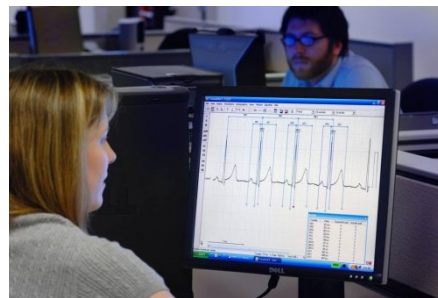


ECG Captured
at Site

Transmitted



Analyzed at
ERT



ECG Results
reported to site
via My Study
Portal





Customer Care

Your Primary Contact Point for ERT Questions

- Machine Technical Support
- Result Inquiries
- Site Information Updates
- Test Transmission
- Web Based Training Inquiries
- Dial the toll free number for your country and press option 1 for cardiac safety assistance

Dedicated Toll-Free Phone and Fax Numbers World-wide

Available **24x7x365** - Multilingual Support

E-mail address: customercare@ert.com



Actions on Equipment Arrival

- Check contents on arrival
 - ELI 150 ECG machine and H12+ Holter device
 - Power Cable, Patient Cable, Telephone Cable
 - Electrodes & ECG paper
 - Flashcards
 - Laminated Quick Reference Guides
 - Training CD
- Plug ECG machine in **(Very Important)**
 - Confirm date and time



Mortara ELI 150

- Stores up to 55 ECGs
- Weighs only 7.2 lbs (3.3 kg)
- Simultaneous acquisition of 12 leads
- Real Time ECG View
- Universal modem
- AC Power or Battery (up to 8 hours)
- Easy demographic entry, recording and transmission



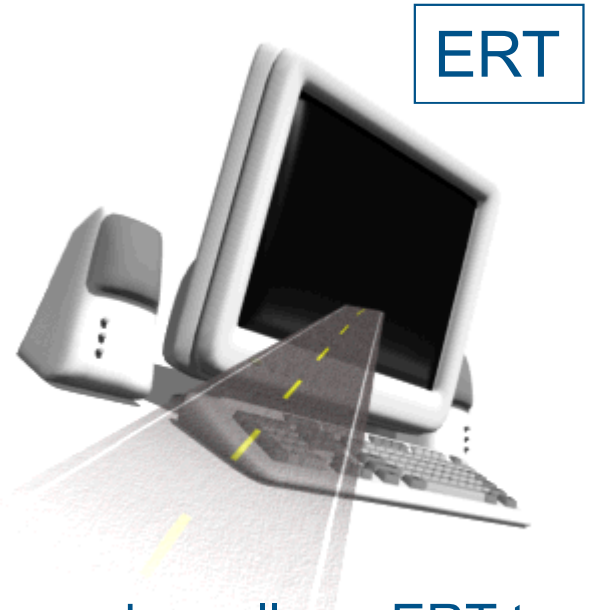
Test Transmission

- ERT recommends completing a test transmission
- A test ECG will already be stored on each machine for this purpose
- Sites should contact ERT customer care if there are any problems transmitting the test ECG



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Investigators Meeting, Barcelona – 20 & 21 January 2011

Your Site



ERT

- This procedure allows ERT to confirm successful ECG transmission from your site, and to assist with any issues prior to first ECG capture



Supplied Quick Guides

Mortara ELI 150 Quick Guide – Sponsor Protocol

v# DDMMYYYY

Entering Patient Data

- 1 Check that the machine is off. Press the "On/Off" key.
- 2 Attach the patient to the machine. Refer to the "Patient Setup" Guide.
- 3 Press the "ID (F1)" key to enter patient demographic information. Enter all patient data as shown in the quick guide.
- 4 Enter the patient's name. If there is no middle name, press the "F2" key.
- 5 Enter the (2) two digit age.
- 6 Enter the patient's birth date (MM/DD/YYYY).
- 7 The patient's Age will be displayed. Press the "F2" key.

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Mortara ELI 150 Quick Guide – Sponsor Protocol

v# DDMMYYYY

Entering Patient Data

- 8 Enter the patient's name. Press the "F2" key to toggle between first and last name.
- 9 Enter the "Visit" number. Press the "F2" key.
- 10 Enter the "Time" of day. Press the "F2" key.
- 11 Press the "Done (F6)" key to save the patient's information.

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Mortara ELI 150 Quick Guide – Sponsor Protocol

v# DDMMYYYY

Recording the ECG

- 1 Check that the machine is off. Press the "On/Off" key.
- 2 Press the "ID (F1)" key to enter patient demographic information. Enter all patient data as shown in the quick guide.
- 3 Press the "Done (F6)" key to complete the patient information screen.
- 4 Instruct patient to lie on the machine. Examine the "Auto" key.
- 5 The Real-Time ECG View will appear. The ECG will automatically print. (WARNING: YOU HAVE A PRINTED ECG FOR QUALITY CHECK.) Press the "Done (F6)" key.
- 6 The unit will prompt you to save the ECG or F3 to delete it. Press the "F3" key to delete the ECG.
- 7 The Real-time ECG view screen and the second ECG will be displayed.
- 8 Press the "Done (F6)" key to save the ECG.
- 9 Press the "Done (F6)" key to save the ECG.

NOTE: Please check the patient's name. A maximum capacity of 55 goes to the next screen.

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Mortara ELI 150 Quick Guide – Sponsor Protocol

v# DDMMYYYY

Transmitting the ECG via Analog Modem

- 1 Attach the phone cord to the analog phone jack (regular fax line) on the wall and the other end into the phone port on the back of the machine.
- 2 Press the "Transmit" Key.
- 3 Press the "Batch (F1)" key. All ECGs that have not been previously transmitted will now be sent.
- 4 View the LCD screen while the transmission is occurring to ensure a successful transmission.
- 5 A successful transmission will show a message at the bottom of the LCD screen. The message will indicate the **Number of ECGs** sent.
- 6 An unsuccessful transmission will show a "Transmission Failure" message. Immediately contact the Customer Care Center.
- 7 When the display returns to the main menu (approximately 5 seconds) press the "(More) F6" key.
- 8 Press the number 1 to Select the Directory of ECGs.
- 9 Verify each ECG has been transmitted by checking each has "PTX" next to it.

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Questions? Call Customer Care: ### ###, Option Number 1

For revision history refer to Investigator guide publication history. TMPL v4 20Aug2000 for use with ELI150 v1.3/1.4 Single

Ensuring Quality Tracings

- Patient Preparation:

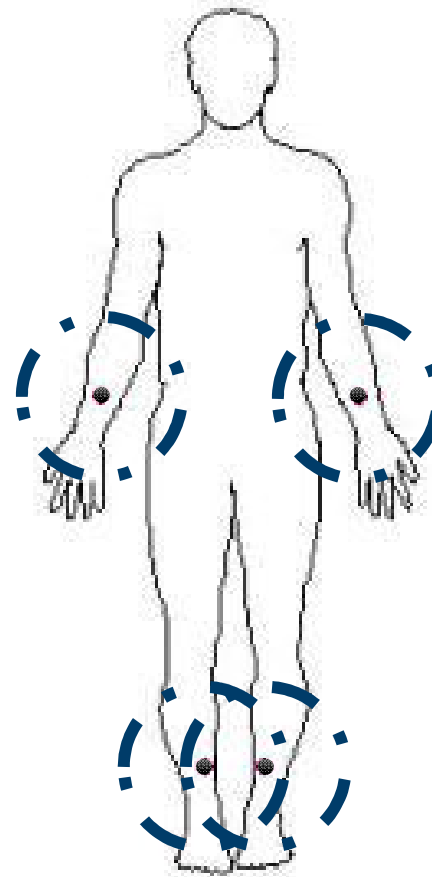
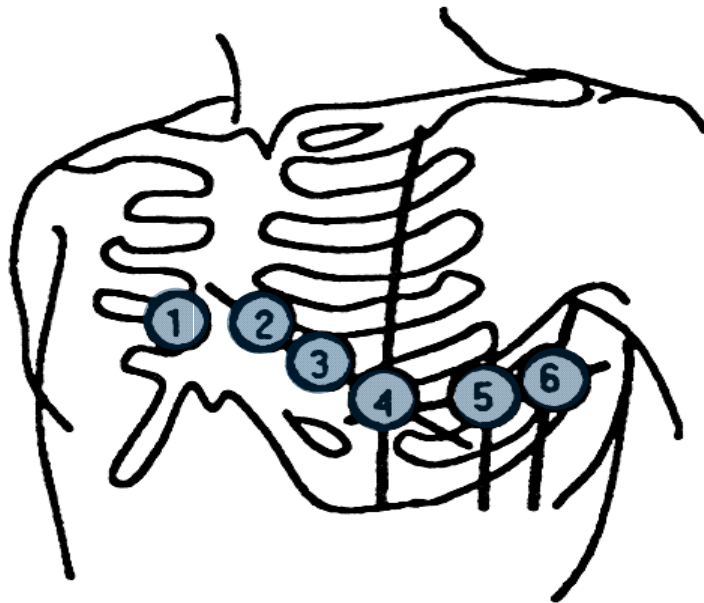
- Skin Preparation
- Proper Electrode Placement
- Good Electrode to Skin Contact
- Remove Jewelry
- Patient in Supine Position Prior to Recording
- No Patient Movement During Recording
- Good Cable Connections (attached properly)
- Avoid Electrical Interference (e.g. Cell phones should be switched off)



Good Quality Tracing



Standard 12-Lead Electrode Placement



ECG Visit Schedule

Actual Visit name	Visit Code
Visit 1 (Screening)	1
VISIT 2 (DAY 1) A	2A
VISIT 2 (DAY 1) B	2B
VISIT 2 (DAY 1) C	2C
VISIT 3 (WEEK 1)	3
VISIT 4 (WEEK 2)	4
VISIT 5 (WEEK 4)	5
VISIT 6 (WEEK 8)	6
VISIT 7 END OF TREATMENT	7
VISIT 8 END OF STUDY	8
UNSCHEDULED	U

Entering Patient Demographics

AC-060A202

PATIENT NUMBER: (12345)

DOB: (MM/DD/YYYY)

AGE AT SCREEN: (99)

GENDER: (MALE/FEMALE)

VISIT: (S)

▲

▼

▶

Req

Direc

Done

F1

F2

F3

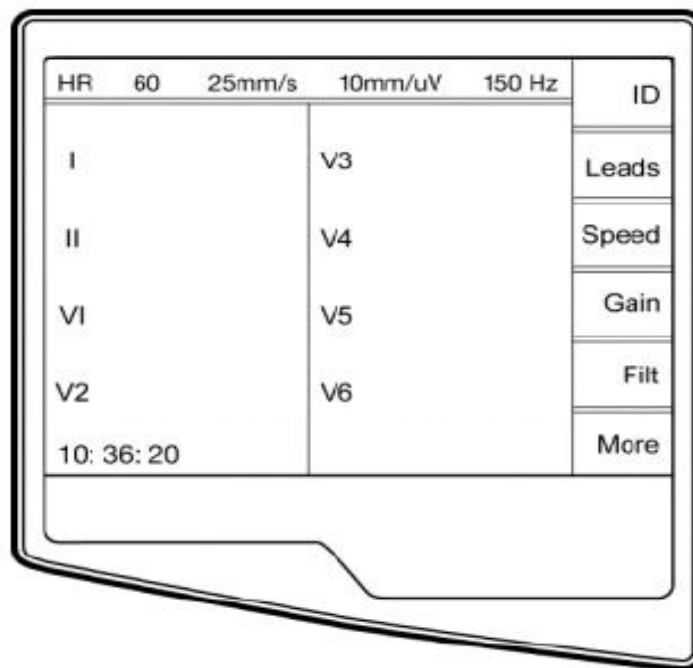
F4

F5

F6

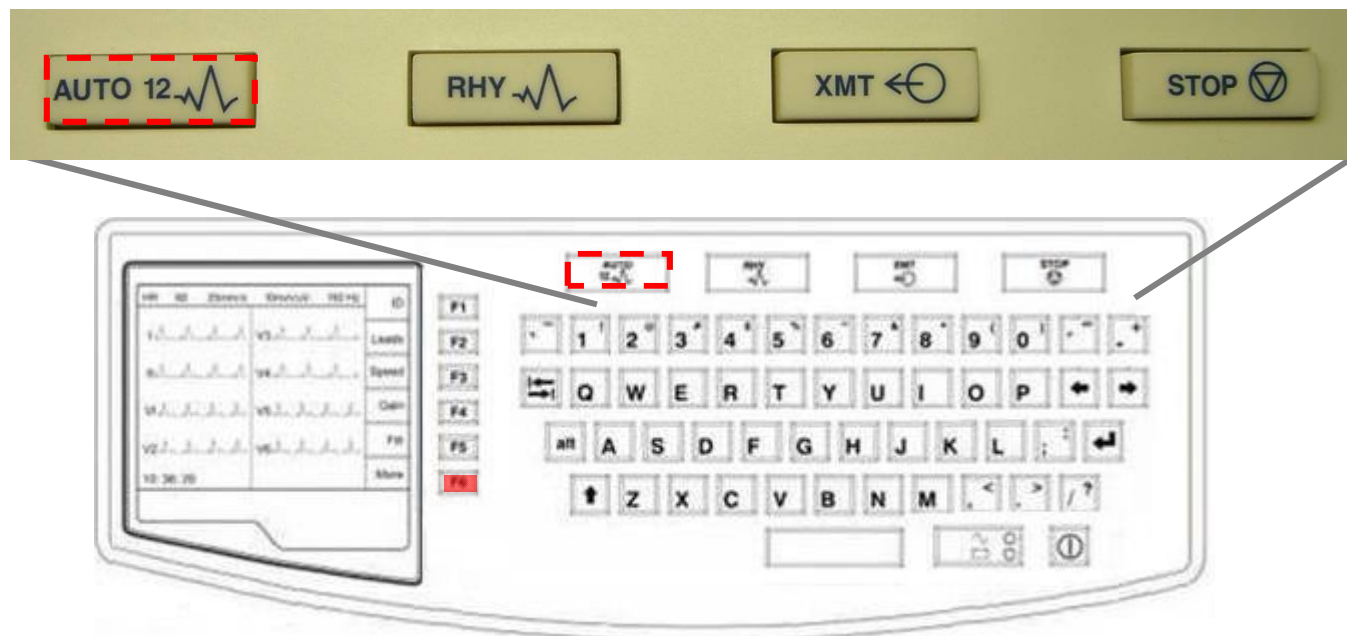
- Press F1 (ID) key to enter patient demography
- Press F6 (DONE) key after last entry

Recording ECGs



- Check the LCD screen to ensure quality

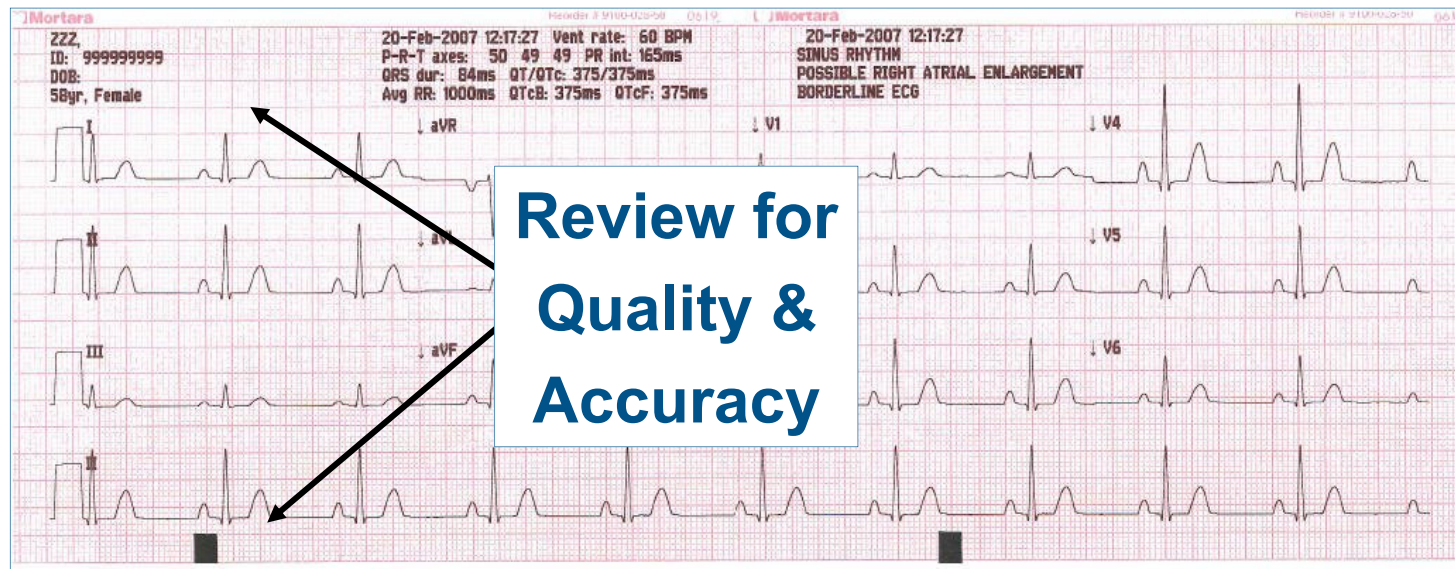
Recording ECGs



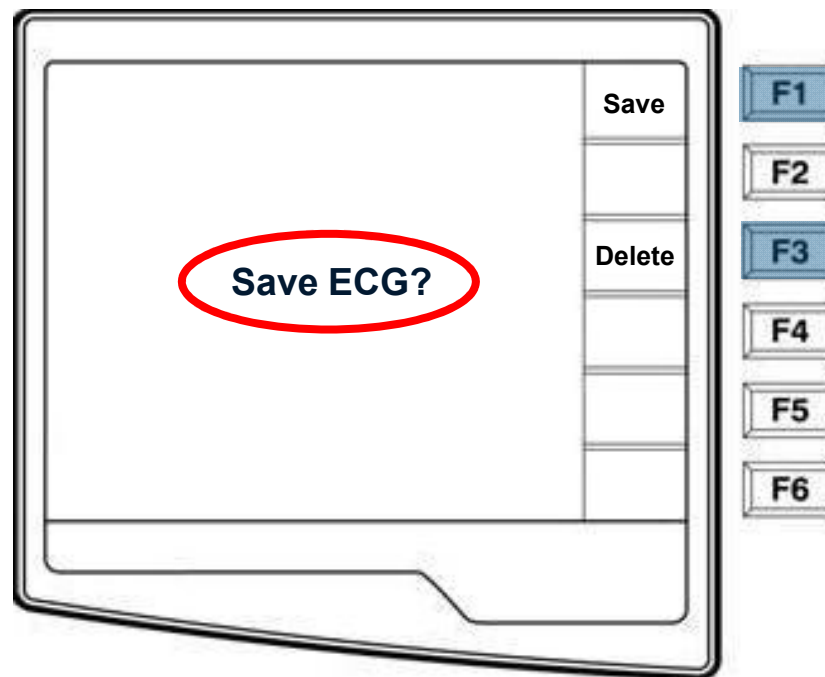
- Press AUTO key to record the ECG
- Press F6 (DONE) key after printing

ECG Print Out

- Standard tracing with 10 second Lead II strip
 - 2 copies of each ECG will print out
 - Z-Fold Heat Sensitive Paper
 - take a photocopy for your permanent records
 - Machine interpretation is given as a guide only



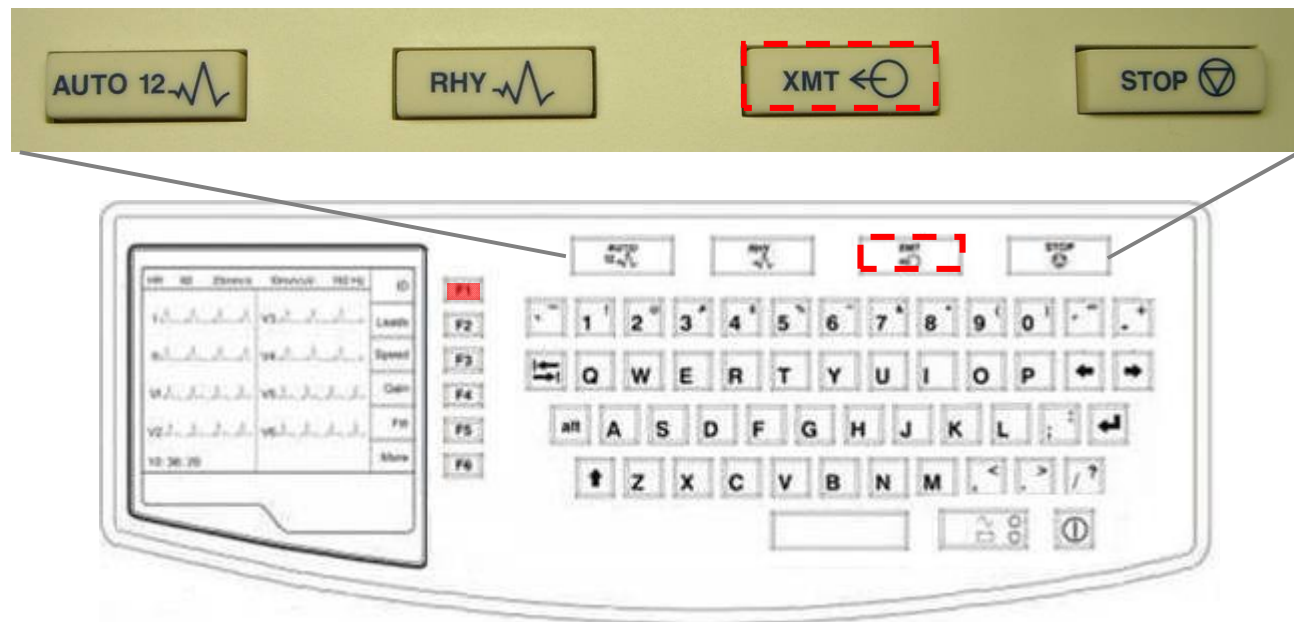
Saving ECGs



The unit will ask “Save ECG?”

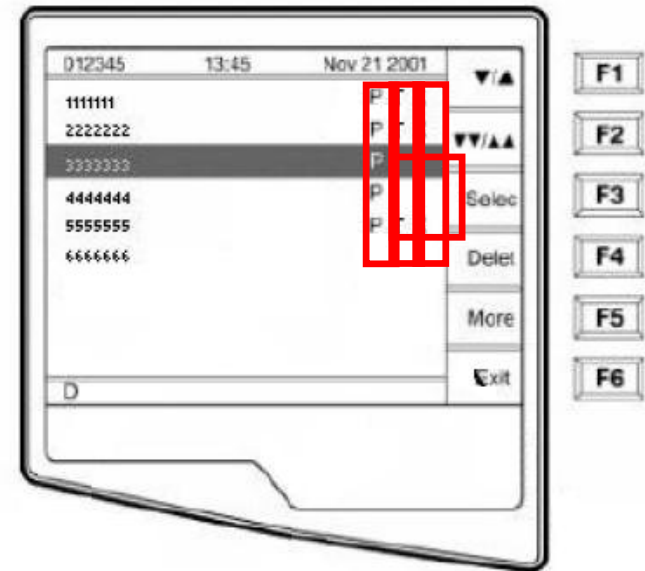
- Press (F1) to Save
- Press (F3) to Delete

Transmitting ECGs



- Plug the device into the phone line.
- Press the XMT key (Transmit key)
- Press the (F1) key to Batch Transmit

Patient Directory



VERY IMPORTANT:

Verify each ECG has been transmitted by checking (P/T/X):

P = Printed

T = Transmitted

X = Marked for deletion

ECG Analysis Summary

Interval Duration Measurements (IDMs)

- RR, PR, QRS, QT
- HR, QTcB and QTcF derived

Cardiologist Interpretation:

- Rhythm
- Ectopy
- Conduction
- Morphology
- Myocardial Infarction
- ST Segment
- T Waves/U Waves
- Physician's Comments



ECG Analysis Report

ECG Analysis Report

Sponsor: DEMO SPONSOR
Protocol: PROTOCOL DEMO2
Account: 051715
Transmittal Number: 63172

Evaluation

Interpretation: Normal

Evaluation By: Marisa Diaz
Evaluation Date/Time: 24-APR-2009 10:27

For Site Use Only.

Investigator Signature: _____ **Date:** _____

Generated on: 24-APR-09 10:32:52

Page 1 of 1

1818 Market St.
Suite 1000
Philadelphia, PA 19103-4001

Pegasus House, Bakewell Road
Peterborough, Cambridgeshire PE2 6YS
United Kingdom

Issued to: C BLUE mdiaz@ert.com; C BLUE mdiaz@ert.com

For Site Use Only.

Investigator Signature: _____ **Date:** _____

Generated on: 24-APR-09 10:32:52

Page 1 of 1

1818 Market St.
Suite 1000
Philadelphia, PA 19103-4001

Pegasus House, Bakewell Road
Peterborough, Cambridgeshire PE2 6YS
United Kingdom

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ECG Results Reporting

My Study Portal ECG reports and waveforms

- The ECG Analysis Report will be provided to the investigator site via My Study Portal within 72 hours
- This excludes weekends and holidays

ECG Reports & Images

ECG Analysis Reports

Source ECG Tracing

ERT
Getting it Done. Right.

ECG Analysis Report

Sponsor: DEMO SPONSOR
Protocol: PROTOCOL DEMO2
Account: 051715
Transmittal Number: 63172

Subject Information

Site ID:	2015	Initials:	ANN
Investigator Name:	BLUE, C	Date of Birth:	15-MAY-1970
Address:	8888 WATER CIRCLE SAN DIEGO CA 92104 United States of America	DI:	50001

Visit:
Collection Date: 16-FEB-2008
Collection Time: 15:33:10

Interval Duration Measurements

Collected By: Diaz, Maria
Tracing Quality: Good Tracing

Lead Analyzed:	II	Mean
Heart Rate (bpm):		60
RR Interval (ms):		1000
PR Interval (ms):		169
QRS Interval (ms):		88
QT Interval (ms):		383
QTc Bazett's (ms):		383
QTc Fredericia's (ms):		383

Evaluation

Interpretation: Normal

Evaluation By: Maria Diaz
Evaluation Date/Time: 24-APR-2009 10:27

For Site Use Only:
Investigator Signature: _____ Date: _____
Generated on: 24-APR-09 10:32:52 Page 1 of 1

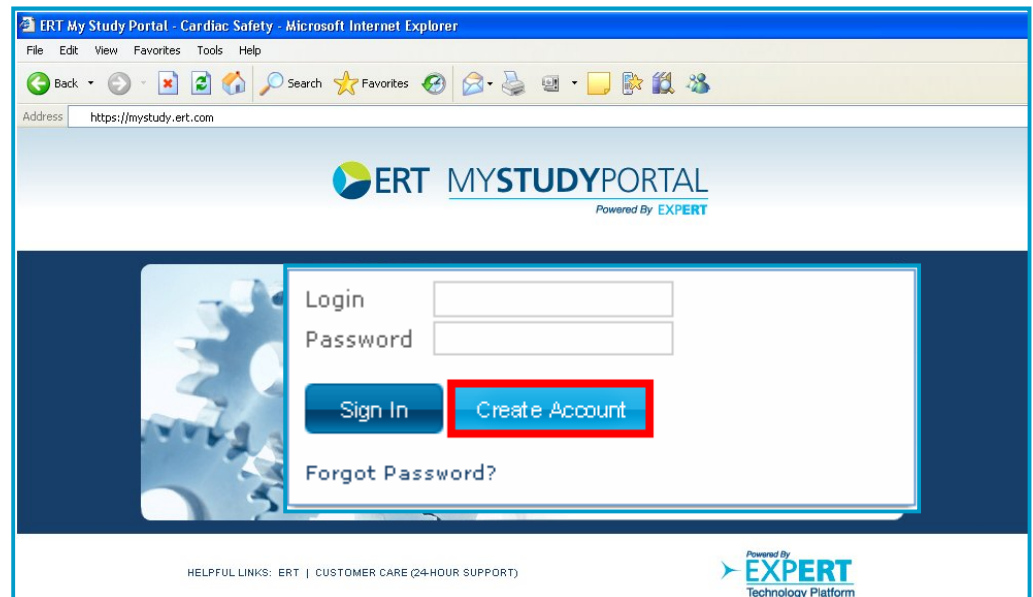
1818 Market St. Suite 1000 Philadelphia, PA 19103-4001	Peggy House, Bakewell Road Peterborough, Cambridgeshire PE2 6YS United Kingdom
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My Study Portal

Creating an account

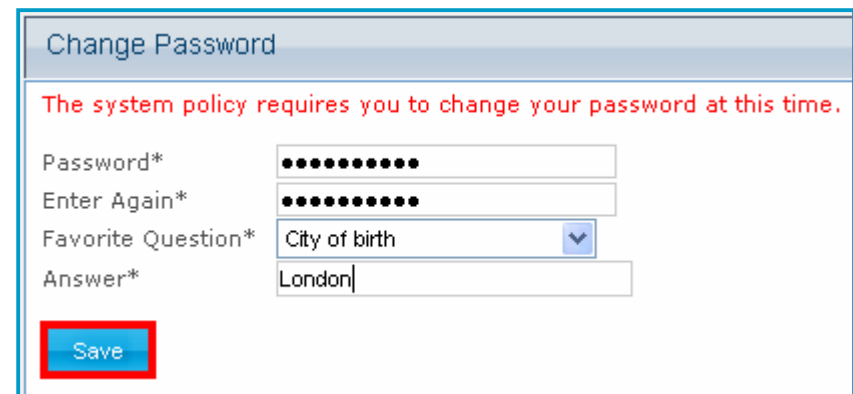
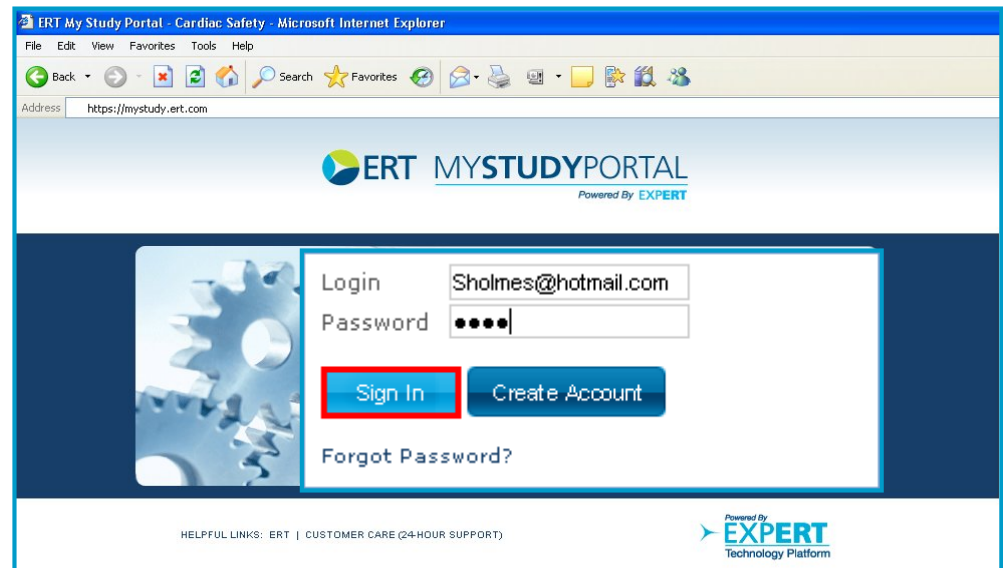
- Access My Study Portal and click on create account
- Enter contact details of Site Qualification entry contact
- Carefully enter the Qualification PIN. This is a 10 digit, case sensitive PIN distributed by the sponsor
- Complete the Text Verification field by copying the number shown into the box provided
- Confirm all details are correct and click “**Save**”
- This creates the user account in My Study Portal



My Study Portal

Logging in

- An email will be sent to each account created in My Study Portal containing the username and a temporary password
- Access My Study Portal, enter the provided login credentials and click **“Sign In”**
- You will be asked to change your password and provide the answer to a favorite question.
- This question will be asked if you forget your password
- Complete these fields then click **“Save”**



My Study Portal

Site Qualification

- Click Site Qualification tab
- Enter the protocol Qualification PIN provided by the Sponsor and click “New Form”



Cardiac Safety ePRO **Site Qualification**

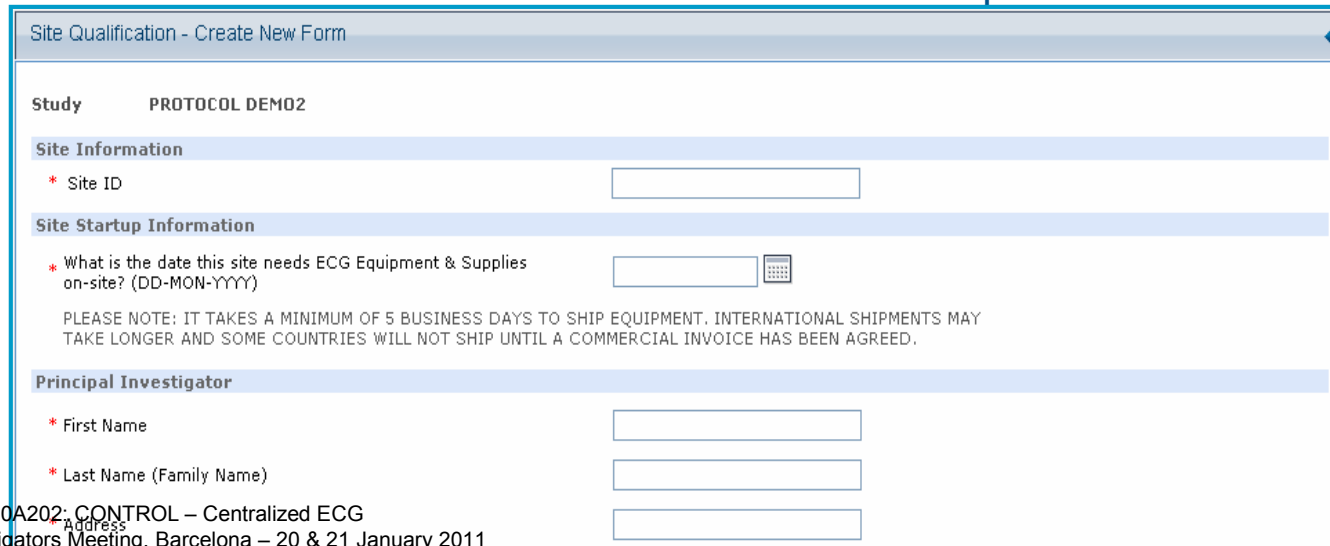
Site Qualification

Qualification PIN:

This is the study qualification code you should have received for access to the study.
Format is 10 alphanumeric digits, case-sensitive (enter both upper and lowercase letters exactly).
If you do not have a qualification PIN, please contact your study manager.

New Form

- The Site Qualification form will be displayed. The SQF entry contact must enter the **site number**, along with the **full site address** and **dialing details**. All fields marked with a **red asterisk *** must be completed




Site Qualification - Create New Form

Study PROTOCOL DEM02

Site Information

* Site ID

Site Startup Information

* What is the date this site needs ECG Equipment & Supplies on-site? (DD-MON-YYYY) 

PLEASE NOTE: IT TAKES A MINIMUM OF 5 BUSINESS DAYS TO SHIP EQUIPMENT. INTERNATIONAL SHIPMENTS MAY TAKE LONGER AND SOME COUNTRIES WILL NOT SHIP UNTIL A COMMERCIAL INVOICE HAS BEEN AGREED.

Principal Investigator

* First Name

* Last Name (Family Name)

* Address

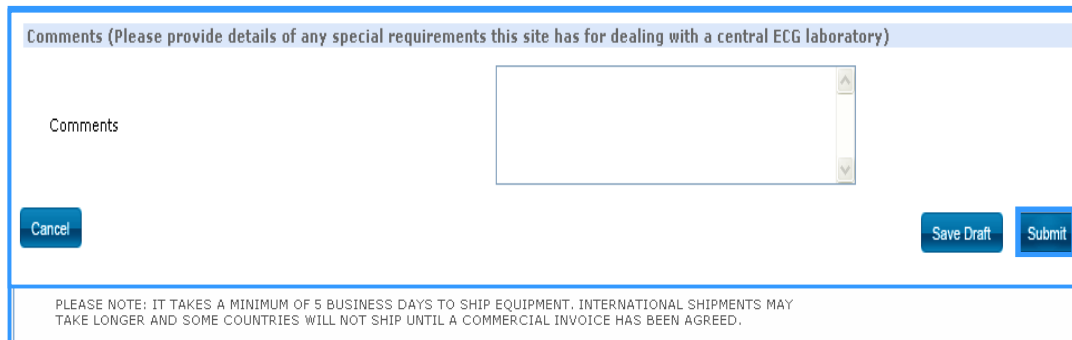
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Investigators Meeting, Barcelona – 20 & 21 January 2011



My Study Portal

Site Qualification

- Complete all required fields and click “Submit”.
- Confirm all details are correct and click “Confirm Submit” to send the form to ERT.



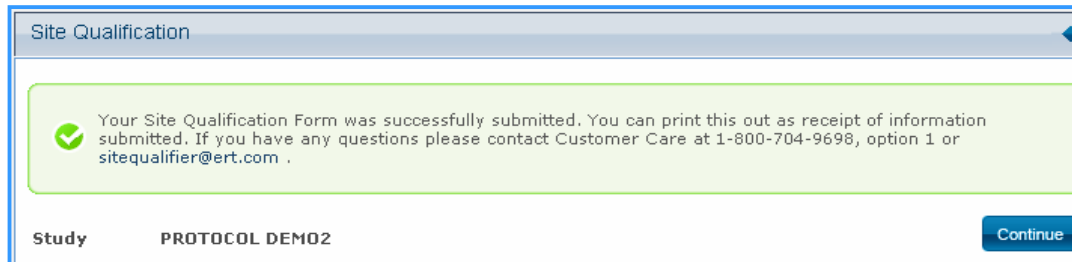
Comments (Please provide details of any special requirements this site has for dealing with a central ECG laboratory)

Comments

Cancel Save Draft Submit

PLEASE NOTE: IT TAKES A MINIMUM OF 5 BUSINESS DAYS TO SHIP EQUIPMENT. INTERNATIONAL SHIPMENTS MAY TAKE LONGER AND SOME COUNTRIES WILL NOT SHIP UNTIL A COMMERCIAL INVOICE HAS BEEN AGREED.

- A confirmation message will be displayed and emailed to the user.



Site Qualification

✓ Your Site Qualification Form was successfully submitted. You can print this out as receipt of information submitted. If you have any questions please contact Customer Care at 1-800-704-9698, option 1 or sitequalifier@ert.com.

Study PROTOCOL DEM02 Continue




- Please allow 5-10 business days for shipping of equipment.
- The Site Qualification Form only needs to be completed once per site



My Study Portal Quick Guides

- Copies of the ERT Guides and Manuals are posted on My Study Portal
- Any modified versions will also be posted here

Reference Materials	
Folder	# of Documents
ERT Communications	1
Study Manuals	8
Equipment Manuals	3
Quick Guides	39
Site Forms	2

Reference Materials - Study: PROTOCOL DEMO2 :: ECG :: Holmes, Sherlock / 0007		
ERT Communications	Study Manuals	Equipment Manuals
Quick Guides	Site Forms	
Results 1 - 3 of 3		
Document	Size	Date Modified
 Machine Manual ELI150v11.3 - v3.pdf	1,108.8k	28-May-2009 15:39:22
 Machine Manual ELI150v12.3 Autofill - v3.pdf	1,116.1k	28-May-2009 15:39:27
 Machine Manual H12+v3 14 12 lead v3.pdf	381.7k	28-May-2009 15:14:20



Avoiding Queries

- Please take care when entering data.
- Be sure to check the demography and visit code information.
- Ensure transmittal forms are completed correctly.
- ECG results will not be available until all queries are resolved.

Responding to ERT Queries

My Study Portal (ECG and ECG Extraction only)

- Sites are able to respond to active queries online using My Study Portal
- Access the “Electronic Query resolution” portlet
- Click the pencil icon to access the query

Cardiac Safety

ePRO



Site Qualification


Electronic Query Resolution

Study: PROTOCOL DEMO2

Investigator: BLUE, C

Site ID: 2015

Initials	Date of Birth	ID1	rand	Collection Date	Transmittal Number	Publish Date	Publish Age (days)
ANN	15-May-1970	S0001	ABBD	20-Feb-2009 11:02:05	63178	03-Feb-2010 14:39:50	14 
ANN	15-May-1970	S0001	ABCD	20-Feb-2009 10:18:18	63176	03-Feb-2010 14:39:50	14 

 Refresh

Queries 1 - 2 of 2



Responding to ERT Queries

My Study Portal (ECG and ECG Extraction only)

- The online query is displayed
- Sites may enter their resolution and submit this to ERT

The screenshot shows the 'Electronic Query Resolution' window. On the left, there are three blue arrows pointing to specific sections: 'Query Description' points to the 'Messages' section, 'Query Response' points to the 'Response' text area, and 'Electronic Signature' points to the login fields. On the right, two blue arrows point to the 'Query Information' table and the 'Query History' table. The interface includes a 'Messages' section with a warning icon and text, a 'Response' section with a text input area, and a 'Query Information' table with fields like ERT Data Coordinator, Sponsor, Study, Investigator, Site ID, Transmittal Number, Visit, Initials, Date of Birth, ID1, rand, and Collection Date. Below the response area is a checkbox for authorizing ERT to resolve the query and login fields for 'Login/Email' and 'Password'. At the bottom are 'Cancel', 'Display Query Queue', and 'Submit' buttons. The 'Query History' table at the bottom right shows a single entry for Hennessey, Yvette.

Query Description

Query Response

Electronic Signature

Query Information

Query History


Query Information			
ERT Data Coordinator:	Hennessey, Yvette		
Sponsor:	DEMO SPONSOR		
Study:	PROTOCOL DEMO2		
Investigator:	BLUE, C		
Site ID:	2015		
Transmittal Number:	63176		
Visit:	/TREATMENT1/DOSE 1		
Initials	ANN		
Date of Birth	15-May-1970		
ID1	S0001		
rand	ABCD		
Collection Date	20-Feb-2009 10:18:18		

Query History			
User Name	Time of Action	Action Type	Action Description
Hennessey, Yvette	03-Feb-2010 14:39:47	Manual Email or Fax	Attempt #1 to Site



Responding to ERT Queries

Paper ECG Submission Form



Paper ECG Submission Form

Complete One Form Per Subject

Client:			
Protocol:			
Account ID:			
Document Version:	1		

COMPLETE THE FOLLOWING:

Investigator:			
Site #:			
Subject ID1:			
Subject ID2:			
Initials:			
DOB:			
Gender:			
Visit (refer to Study Manual):			
Collection Date:			
Collection Time:			
Other:			

RETURN FORM TO ERT (via courier):

Recipient:	North/South America:	All other Countries:
	ERT Attention: Data Coordination	ERT Attention: Data Coordination
Recipient Address:	1818 Market Street, Suite 1000 Philadelphia, PA 19103-3638 USA	Pegasus House, Bakewell Road Orton Southgate Peterborough PE2 6YS UK
Recipient Phone:	+1-800-704-9698, option 1 (US/Canada) +1-908-595-2020, option 1 <small>(Refer to Study Manual for Toll Free Country Specific No.)</small>	+1-800-704-9698, option 1 (US/Canada) +1-908-595-2020, option 1 <small>(Refer to Study Manual for Toll Free Country Specific No.)</small>

Site Representative _____ Site Representative Signature _____ Date _____

(PM to remove if not GMB/Fully Auto study)

ERT Internal Use ONLY			
Was ECG(s) collected using the ERT supplied ECG machine for protocol above	<input type="checkbox"/> Yes <input type="checkbox"/> No	Initials:	Employee ID:

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- If you receive a query for a missing ECG
- Check Patient Directory on the machine
- If the ECG is no longer stored in the ECG Machine, send one of the two original tracings to ERT along with a completed Paper ECG Submission Form
- Respond to the query with the Tracking information



Responding to ERT Queries

Data Clarification Form (Holter Arrhythmia only)


 ERT Getting It Done. Right.		Data Clarification Form New, 22-FEB-2007							
Results will not be available until query is resolved.									
To: Kate Ward	Fax:	Email: kward@ert.com							
From: Kathleen Ward									
Sponsor: UAT	Protocol: C1236(Active)								
Investigator Name: Ward, Kate	Site ID: 5278								
<u>Query:</u> Please confirm if v7 was/was not performed for this patient. If performed please retransmit. ECGs If unable to retransmit, courier the original ECG to eRT for processing. Thank you.									
Visit / not performed									
Signature: 		Date: 18-July-2007							
Please complete the resolution section, sign and date this form, then return this form to Philly, Data Coordination; Fax: 866 745 0810									
<div>Generated on: 22-FEB-2007 13:44:14</div> <div>Page 1 of 1</div> <table border="1"><thead><tr><th colspan="3">CORPORATE OFFICES</th></tr></thead><tbody><tr><td>30 South 17th Street Philadelphia, PA 19103-4101 United States of America Phone : 1-800-704-9698 Fax : 1 215 972 0414</td><td>1150 U.S. Hwy 22 East Bridgewater, NJ 08817-2912 United States of America Phone : 1-800-704-9698 Fax : 1 908 704 8276</td><td>Pegasus House, Bakerwell Road Peterborough, Cambridgeshire PE2 6YS United Kingdom Phone : 001 908 596 2026 Fax : 011-44-1733238782</td></tr></tbody></table>				CORPORATE OFFICES			30 South 17th Street Philadelphia, PA 19103-4101 United States of America Phone : 1-800-704-9698 Fax : 1 215 972 0414	1150 U.S. Hwy 22 East Bridgewater, NJ 08817-2912 United States of America Phone : 1-800-704-9698 Fax : 1 908 704 8276	Pegasus House, Bakerwell Road Peterborough, Cambridgeshire PE2 6YS United Kingdom Phone : 001 908 596 2026 Fax : 011-44-1733238782
CORPORATE OFFICES									
30 South 17th Street Philadelphia, PA 19103-4101 United States of America Phone : 1-800-704-9698 Fax : 1 215 972 0414	1150 U.S. Hwy 22 East Bridgewater, NJ 08817-2912 United States of America Phone : 1-800-704-9698 Fax : 1 908 704 8276	Pegasus House, Bakerwell Road Peterborough, Cambridgeshire PE2 6YS United Kingdom Phone : 001 908 596 2026 Fax : 011-44-1733238782							

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Responding to ERT Queries

Data Revision Request Form

 Data Revision Request Form		
Subject Data		
Initials		
Date of Birth		
Gender		
Subject Number		
Screening/ Randomization Number		
ECG/Holter Visit		
ECG/Holter Date		
ECG/Holter Time		

	Signature	Date
Site (failure to provide signature will prevent edits being made)		
ERT - PM (approval required if date or time change, unless reason is daylight savings)		

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Investigators Meeting - August 1st, 2012 - 11:00 AM

ERT

Return of ECG Equipment

- Save shipping materials for returning equipment at end of study
- Return the ECG machine including cables via courier
- Sites are not required to return reference materials or electrodes





Thank You

